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(54) Title: FORMULATIONS FOR MEDIATING INFLAMMATION AND FOR REDUCING BLOOD CHOLESTEROL

(57) Abstract: The invention provides formulations for mediating inflammation and for lowering blood cholesterol. For example, inflammation of the intestine, retina or neural tissues, may be mediated. Further the formulations are effective in decreasing blood cholesterol absorption. The formulations comprise at least one ganglioside, which may be selected from the group consisting of: GD3, GM1, GM2, GM3, GD1b, NANA, and sialic acid. The invention further provides a method of treating or preventing inflammatory diseases by delivery of at least one ganglioside to a subject in need thereof, and a method of reducing blood cholesterol in a subject be delivery of a ganglioside-containing formulation. The formulation of the invention may be used to supplement foods or liquids, and may for example be used in preparation of infant formula or foods.



International Application No CT/CA2004/000375

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/7032 A61P29/00 A61P3/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) $IPC \ 7 \ A61K$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, WPI Data, PAJ, EMBASE

C. DOCUMI	ENTS CONSIDERED TO BE RELEVANT		·
Category °	Citation of document, with indication, where appropriate, of	f the relevant passages	Relevant to claim No.
Х	BUCOLO C ET AL: "EFECTS OF NOCULAR ALLERGIC INFLAMMATION RABBIT" JOURNAL OF OCULAR PHARMACOLOG LIEBERT, INC. NEW YORK, NY, UVOl. 9, no. 4, 1993, pages 32 XP000570599 ISSN: 8756-3320 page 321, abstract	1-6, 10-18	
X	EP 0 351 784 A (FIDIA SPA) 24 January 1990 (1990-01-24) claims 1,2	-/	1-3,5,6, 10-12, 14-18
	er documents are listed in the continuation of box C.	X Patent family members are listed in	annex.
"A" documer conside filing da filing	nt which may throw doubts on priority claim(s) or s cited to establish the publication date of another or other special reason (as specified) nt referring to an oral disclosure, use, exhibition or	"T" later document published after the inter or priority date and not in conflict with the cited to understand the principle or the invention "X" document of particular relevance; the claranot be considered novel or cannot involve an inventive step when the document of particular relevance; the claranot be considered to involve an inventive step when the document is combined with one or more ments, such combination being obvious in the art. "&" document member of the same patent for the same patent	airned invention be considered to ument is taken alone airned invention entive step when the e other such docu- s to a person skilled
Date of the actual completion of the international search		Date of mailing of the international search	ch report
36	June 2004	11	10. 2004
lame and m	alling address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Beranová, P	•

International Application No PCT/CA2004/000375

Category °	Lation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Jalegoly	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	OLIVEIRA ALEXANDRE L R ET AL: "GM-1 ganglioside treatment reduces motoneuron death after ventral root avulsion in adult rats" NEUROSCIENCE LETTERS, vol. 293, no. 2, 27 October 2000 (2000-10-27), pages 131-134, XP002286616 ISSN: 0304-3940 page 131, abstract	1-3,5,6, 10,12, 14-18
X	WO 95/20959 A (US ARMY) 10 August 1995 (1995-08-10) claims 1,5	1,3,5,6, 10,12, 14,15, 17,18
,	-	
(GB 2 289 274 A (ERBA CARLO SPA; PHARMACIA SPA (IT)) 15 November 1995 (1995-11-15)	1,3,5,6, 10,12, 14,15, 17,18
	claim 1 page 7, line 11	
	DATABASE WPI Section Ch, Week 198931 Derwent Publications Ltd., London, GB; Class A96, AN 1989-225642 XP002286617 & JP 01 163125 A (SHISEIDO CO LTD) 27 June 1989 (1989-06-27) abstract	1,3,5,6, 10,12, 14,15, 17,18
	WO 90/09185 A (ANGIO MEDICAL CORP) 23 August 1990 (1990-08-23) claims 1,5	1,5

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-18

Use of gangliosides for the treatment of inflammation

2. claims: 19-28

Use of gangliosides for reducing plasma cholesterol

International application No. PCT/CA2004/000375

Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)
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This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 19-28 because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 10 - 14 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple Inventions in this international application, as follows:
see additional sheet
·
1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
A. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the Invention first mentioned in the claims; it is covered by claims Nos.: 1-18
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Although claims 10 - 14 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.

Information on patent family members

International Application No PCT/CA2004/000375

Patent document		Publication		Patent family		Publication
clted in search report		date		member(s)		date
EP 0351784	Α	24-01-1990	IT	1224513 B	3	04-10-1990
			AT	97812 1	Γ	15-12-1993
			AU		32	04-06-1992
	•		AU	3819089 A	1	25-01-1990
			DE)1	13-01-1994
			DE		2	01-06-1994
			DK	354589 A	-	20-01-1990
			EP	0351784 A		24-01-1990
			ES	2061821 T		16-12-1994
			JP	2078622 A		19-03-1990
	•		PH	26117 A		24-02-1992
			ZA	8905367 A	١	25-04-1990
WO 9520959	Α	10-08-1995	US	5631283 A		20-05-1997
			WO	9520959 A		10-08-1995
			US	6066323 A		23-05-2000
GB 2289274	Α	15-11-1995	NONE		~~~~	
JP 1163125	Α	27-06-1989	JP	2684179 B	 2	03-12-1997
WO 9009185	Α	23-08-1990	ΑU	5160590 A		05-09-1990
			WO	9009185 A	4	23-08-1990